

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1833V
UNPUBLISHED

LISA HEJNA,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: March 23, 2022

Special Processing Unit (SPU);
Dismissal; Statutory Six-Month
Severity Requirement; Insufficient
Evidence; Influenza (Flu) Vaccine;
Shoulder Injury Related to Vaccine
Administration (SIRVA).

Michael G. McLaren, Black McLaren Jones Ryland & Griffee, P.C., Memphis, TN, for Petitioner.

Adriana Ruth Teitel, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On November 29, 2018, Lisa Hejna filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that as a result of an influenza (“flu”) vaccine received on October 5, 2017, she suffered a shoulder injury related to vaccine administration (“SIRVA”) as defined on the Vaccine Injury Table (the “Table”). Petition (ECF No. 1) at

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Preamble. The case was assigned to the Special Processing Unit (“SPU”) of the Office of Special Masters.

For the foregoing reasons, I find that despite receiving a full and fair opportunity to develop her claim, Petitioner has provided insufficient proof of severity of injury, as required for all Vaccine Act claims. See Section 11(c)(1)(D)(i) (petitioners must demonstrate “residual effects or complications of [the injury alleged for more than six months after the administration of the vaccine,” to demonstrate eligibility to seek compensation from the Vaccine Program).³ Respondent’s motion to dismiss the petition on that basis (ECF No. 35) is therefore granted.

I. Relevant Procedural History

Petitioner acknowledged at the outset of the case’s initiation that approximately three months after vaccination, after suffering complications with a pregnancy, she had discontinued all formal medical treatment for the injury alleged. Petition at ¶¶ 6-8. Nevertheless, Petitioner alleged ongoing, intermittent shoulder pain. *Id.* at ¶¶ 9-10.

In February 2019, Petitioner was first directed⁴ to file any outstanding medical records, affidavits, or other evidence of severity. ECF Nos. 10, 12. In April 2019, Petitioner filed urgent care, obstetrics, and gynecology records. Exs. 8-9. By July 2019, however, after five months of efforts, she advised that “due to the unavailability or lack of timely cooperation from possible witnesses,” she would only be able to rely on the existing record “for the time being.” ECF No. 20 at 1. In October 2019, Respondent opposed compensation, pointing to the lack of evidentiary support. ECF No. 26. Petitioner repeated that she was not working to obtain additional evidence, but she reserved the right to do so later. ECF No. 27. Later, it was decided that Respondent would file the Rule 4(c) report to demonstrate to Petitioner that severity was the primary issue in the case, and that additional evidence on that point was “vital.” ECF No. 30.

In February 2020, Petitioner filed a statement from her mother (Ex. 10), but again declined to file any additional evidence at that time (while reserving the right to do so after Respondent filed his Rule 4(c) Report). ECF No. 32.

³ Petitioner does not allege, nor would the evidence support, either alternative for establishing the severity requirement: that the alleged injury resulted in death, or “inpatient hospitalization and surgical intervention.” Section 11(c)(1)(D)(ii), (iii).

⁴ The claim was originally assigned to then-Chief Special Master Dorsey (now Special Master Dorsey), in her purview overseeing the SPU. In early October 2019, the case was reassigned to me as the current Chief Special Master.

Approximately sixteen (16) months after the petition's filing, on May 1, 2020, Respondent filed his Rule 4(c) Report, formally contending therein that Petitioner had not established the threshold severity requirement, making her ineligible for entitlement. Rule 4(c) Report (ECF No. 34). Respondent also filed a motion to dismiss Petitioner's claim on the same grounds. Motion to Dismiss (ECF No. 35). Petitioner filed a Response (ECF No. 36), but no additional evidence. Respondent then filed a Reply (ECF No. 37). The matter is now ripe for adjudication.

II. Contemporaneous Medical Records

The medical records reflect that upon receiving the subject flu vaccine, Petitioner was almost 34 years old. She managed an eye care center owned by MedStar, a health system in the Washington-Baltimore metropolitan area. Ex. 3 at 1. She had health insurance through her employment (see e.g., Ex. 4 at 13), but rarely sought medical care.

The first medical encounter in evidence is from June 9, 2017, when Petitioner presented to a MedStar urgent care facility reporting left axillary pain since a fall six days earlier. Ex. 3 at 1. A chest x-ray did not reveal any fracture or other injury. *Id.* She was prescribed ibuprofen for pain and instructed to follow up with a primary care provider in the next three to five days. *Id.* Then, on August 9th, Petitioner presented to an internal medicine physician affiliated with MedStar for a new patient appointment and annual examination. Ex. 6 at 1-34. On September 12th, the physician addressed gynecological matters, including that Petitioner was trying to conceive. *Id.* at 35-64.

On October 5th, a pharmacy employee administered the subject flu vaccine into the muscle of Petitioner's left arm. Ex. 2 at 1. Twenty-five (25) days later, on October 30th, Petitioner presented to the MedStar urgent care facility to address "[l]eft shoulder pain after flu shot." Ex. 3 at 3. She recounted that the pain began "immediately" upon vaccination; her arm was "slightly sore for 1-2 days but then resolved"; and then she developed left shoulder pain with movement. *Id.*

On exam, Petitioner complained of pain particularly upon internal and external rotation and lifting overhead. Ex. 3 at 3. She had been taking ibuprofen approximately three times a day "with no relief." *Id.* She reported current pain of 9/10. *Id.* An urgent care physician assessed Petitioner with left shoulder tendinitis which should be managed with rest, ice, compression, and elevation ("RICE"); continued use of ibuprofen; and a newly prescribed muscle relaxant. *Id.* at 4. Petitioner was also told to follow up with a sports medicine specialist. *Id.*

At a November 7th initial consult with a MedStar sports medicine physician, Petitioner reported pain upon vaccination, which after one to two days “moved superiorly towards the left lateral shoulder without significant radiation down the arm.” Ex. 4 at 1. *Id.* On exam, she could actively abduct the shoulder to 110 degrees, which could be extended passively to 160 degrees “with painful arc.” *Id.* at 2. She reported decreased pain of 5–6/10. *Id.* The sports medicine physician assessed rotator cuff tendinitis, but did not perceive tearing, and therefore did not order an MRI. *Id.* After the physician “outlined all manner of conservative treatment options,” Petitioner “defer[red] new medication nor cortical steroid injections for now,” in favor of physical therapy (“PT”), also within the MedStar health system. *Id.* The physician recommended that if Petitioner had “no significant [improvement]” with PT within 4-6 weeks, she should follow up and undergo an MRI. *Id.*

Two months after the sports medicine consult, on January 8, 2018, Petitioner presented for a PT initial examination. Ex. 4 at 10. She again reported left shoulder injury since a flu shot. *Id.* Early anti-inflammatories (e.g., ibuprofen) had “helped reduce pain to present status,” specifically, pain that was worst in the morning especially after sleeping, as well as with activities such as removing her shirt and reaching across her body. *Id.* Her pain was at best 0/10 and at worst 3/10. *Id.* She was “not currently taking any medications.” *Id.* On exam, she had continued limitations on internal and external rotation, positive impingement signs, and “slight” joint mobility restrictions. *Id.* at 11-12. The physical therapist recommended an initial home exercise program (“HEP”) and up to two formal sessions per week for six weeks – e.g., until approximately February 19th. *Id.* at 12, 6-8. The record also notes that Petitioner was seven weeks pregnant. *Id.* at 10.

At the second PT session on January 15th, Petitioner reported some soreness, but “no aggravation of shoulder [symptoms].” Ex. 4 at 4. The therapist provided “cues” on technique, but Petitioner “otherwise tolerated [treatment] well, and reported improved [active range of motion].” *Id.* The record does not reflect her pain rating or specific physical exam findings. *Id.*

While the therapist had planned a course of treatment running to approximately mid-February, January 15th proved to be the last date – of physical therapy or any other medical care – documenting a left shoulder injury. On April 4, 2018, the therapist recorded: “Pt had pregnancy issue, did not return to PT, and is discharged due to time elapsed since last attended appt.” Ex. 4 at 3.

The only subsequent medical records, dating from approximately September 2018 through March 2019, are from obstetrics and gynecology. Those records reflect that Petitioner suffered a miscarriage in the tenth week of pregnancy, in February 2018. See,

e.g., Ex. 8 at 1, 14. The records are concise, focused on a subsequent pregnancy, and do not reflect any complaints or objective findings relating to Petitioner's left shoulder. See *generally* Ex. 8.

III. Witness Statements

In an affidavit completed on November 29, 2018, Petitioner recalled that after her physical therapy sessions, she “had an issue with [her] pregnancy that prevented [her] from continuing therapy.” Ex. 1 at ¶ 8. Afterwards, she “continued to perform exercises at home and to take medication as needed/able.” *Id.* She was discharged from physical therapy “due to [her] inability to return at the time.” *Id.* at ¶ 9. Petitioner stated that as of November 2018, she continued to suffer from “intermittent” shoulder pain and reduced range of motion, for which she continues to perform home exercises and she takes “prescriptions and/or over the counter” pain treatments. *Id.* at ¶¶ 10-11. She stated that her pain had “impacted her ability to sleep, work, and enjoy life in general.” *Id.* at ¶ 11.

Petitioner also submitted what appears to be an excerpt from an email written by her mother. Ex. 10. It is date-stamped April 17, 2019 and reads in full: “To whom it may concern: In 2018 my daughter, Lisa Hejna, had a medical issue which prevented her from finishing physical therapy. The issue caused her physical and emotional pain. Unfortunately, this was something unexpected.” *Id.*

IV. Applicable Legal Standard

The petitioner carries the burden of establishing the matters required in the petition by a preponderance of the evidence. Section 13(a)(1)(A). One such requirement is “documentation demonstrating that [the petitioner]⁵ ... suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” Section 11(c)(1)(D)(i); see also *Black v. Sec’y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the “potential petitioner” must not only make a *prima facie* case, but clear a jurisdictional threshold, by “submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case”), *aff’d*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Congress has stated that the severity requirement was designed “to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.” H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N.

⁵ Or other vaccinee, e.g., a minor or other person who is unable to represent his or her own interests, on behalf of whom the claim is brought.

2313–1, 2313–373, cited in *Cloer v. Sec’y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied*, 132 S.Ct. 1908 (2012); *Wright v. Sec’y of Health & Human Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

The Act prohibits finding a petition requirement “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” Section 13(a)(1). Medical records must be considered, see Section 13(b)(1), and are generally afforded substantial weight. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). However, the Federal Circuit has recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

It is thus certainly the case that factual matters required to prove elements of a Vaccine Act claim may be established by a *mix* of witness statements and record proof, with the special master required to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184 (2013) (citing Section 12(d)(3); Vaccine Rule 8), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

V. Parties’ Arguments

Respondent maintains that Petitioner is not eligible to seek compensation under the Vaccine Act because there is insufficient evidence of residual effects or complications for more than six months after the administration of the vaccine, or past April 5, 2018. Rule 4(c) Report at 5. Indeed, Respondent observes that Petitioner has “not submitted any medical records or other evidence that substantiates the assertions that her shoulder pain persisted *past her January 15, 2018, PT evaluation.*” *Id* (emphasis added). Respondent also points out that Section 13(a)(1) prohibits awarding compensation based solely on a petitioner’s own claims. *Id*. The only other non-medical evidence – the statement from her mother – offered herein is limited to confirming the reason why Petitioner stopped PT, and thus “does not address whether Petitioner continues to experience shoulder pain or when it resolved.” *Id*. at 6.

Petitioner argues in response that she is not required to receive ongoing medical treatment for six months under the Act. Response at 2. She thus contends that she has fulfilled the six-month severity requirement “via explanation of home treatment and the existence of another medical issue that prevented active treatment for her shoulder.” *Id*. She also proposes that determining severity at this juncture is “premature,” because

“there is a material issue of disputed fact.” She thus asks that I deny Respondent’s motion to dismiss at this time, in favor to holding the issue’s resolution until “the appropriate time,” when testimony from Petitioner and “other witnesses she may locate and present, including her mother,” may be obtained. Response at 2-3.

In his reply, Respondent acknowledges that Petitioner’s other medical issue in 2018 might “explain why there was a delay in her seeking treatment for her shoulder pain,” but disputes that it can be “relied on to offset the utter lack of a single piece of evidence that corroborates Petitioner’s assertion that she experienced shoulder pain for at least six months.” Reply at 3. Petitioner’s word alone at that point is “statutorily insufficient.” *Id.* Respondent also emphasizes the amount of time Petitioner has already received to substantiate this matter. *Id.*

VI. Analysis

I note preliminarily that Vaccine Program claimants are directed at the outset of a case’s filing to provide “all available” medical records, and non-medical supplemental evidence (such as affidavits) alongside the petition. Section 11(c); Vaccine Rule 2(c)(ii).⁶ Here, Petitioner not only had opportunity to prepare her claim prior to filing, but was repeatedly put on notice over the subsequent sixteen (16) months that severity was an issue to be addressed. Yet even after Respondent completed his formal review and proposed severity might be dispositive of the claim, Petitioner has not submitted additional evidence or established why additional time is merited to obtain such evidence. It thus cannot be denied that Petitioner has had a “full and fair opportunity” to support her position. Vaccine Rule 3(b).

As it stands, the filed medical records suggest overall that while Petitioner may in fact have experienced a SIRVA, it was a less serious injury that was improving over time, and thus did not necessarily require formal medical treatment to resolve. Indeed, she was initially told to follow a home exercise program (in addition to the formal sessions that were discontinued) until only mid-February 2018 – which would have been only four and one-half months after vaccination. There was thus some medical expectation that treatment of the injury might not be needed for a substantial period of time.

In addition, the record does not corroborate Petitioner’s severity assertions. She discontinued treatment for her shoulder injury following her pregnancy complications in early 2018, and there is no subsequent medical record proof that the injury demanded *any* additional medical evaluation. No records show a single follow-up visit for evaluation

⁶ Vaccine Rule 2(c)(2) specifically provides that the petition “must be accompanied” by medical records supporting the allegations therein. If the petition “does not rely on medical records alone but... in any part” on witness testimony, that testimony shall be set forth in “detailed affidavits.”

of her shoulder symptoms (in comparison to the many records between October 2017 and January 2018 establishing symptoms and treatment).

Petitioner makes two arguments to support severity, but neither are sufficiently persuasive. First, she notes that pregnancy complications caused her to terminate her SIRVA treatment prematurely. I deem this a reasonable explanation for a gap or delay in treatment. But it cannot outweigh the complete, subsequent absence of record proof corroborating that the injury persisted in accordance with the Act's requirements. Indeed, the subsequent treatment that Petitioner *did* receive for obstetrics and gynecology is itself harmful to her claim. The records pertaining to such treatment filed in this case are cursory - and they would not be expected to detail distinguishable problems, like shoulder pain. but the very *fact* that Petitioner did pursue care for current medical concerns underscores the significance of the absence of evidence of subsequent SIRVA treatment.

Second, Petitioner points to the witness statements she offers to establish severity, stressing in connection that the Vaccine Act does not require proof of continuous formal medical treatment throughout the first six months after vaccination. *Accord Kirby*, 997 F.3d at 1383 (accepting that a petitioner may "reac[h] maximum medical improvement and thus exhaust[t] all available treatment"). This is correct - Petitioner was never limited to proving her case by medical records *alone*. But it is reasonable to evaluate the probative weight witness statements merit, especially in light of the totality of filed record evidence.

Here, those statements do not outweigh the inference the records permit about the lack of severity. Petitioner's mother's statement, for example, while further confirming the occurrence of a separate medical issue, did not go towards the critical question of shoulder pain persisting for at least six months. Otherwise, and despite many opportunities to find more evidence, Petitioner offers only her own witness statement, which by itself cannot establish severity (especially where, as here, the record proof of treatment ceases nearly three months before the six-month cut-off date).

I am opting to resolve this issue on the filed record (which includes witness statements), and over Petitioner's request that I allow those witnesses to testify in person. There is ample precedential support for my determination not to conduct a fact hearing. *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Human Servs.*, *see also v. Hooker Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n. 19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum.*

Servs., 38 Fed. Cl. 3 97, 402-03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991). I do not conclude from the existing witness statements, and lack of record corroboration, that live testimony would likely allow an alternative resolution of this case.

VII. Conclusion

Petitioner has presented insufficient proof to establish the six-month severity requirement. Section 11(c)(1)(D). Therefore, she is ineligible to pursue compensation under the Program and Respondent's motion to dismiss (ECF No. 35) is **GRANTED**. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.⁷

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

⁷ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.